

CHARACTERISTICS AND ALLOCATION OUTCOMES OF PATIENTS ASSESSED FOR THE
RENAL REPLACEMENT THERAPY AT GROOTE SCHUUR HOSPITAL (2008-2012).

An audit of Dialysis Rationing

by

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List of Abbreviations

ARV	Anti-retroviral
BMI	Body Mass Index
CD4	Cluster of Differentiation
CKD	Chronic Kidney Disease
CMV	Cytomegalovirus
ESKD	End Stage Kidney Disease
HBsAg	Hepatitis B surface antigen
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
RRT	Renal Replacement Therapy

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Abstract

Background. End Stage Kidney Disease (ESKD) is a global public health problem with an enormous economic burden. In resource limited settings like South Africa management of End Stage Kidney Diseases is rationed to the most transplantable candidates. Racial and socio-economic inequalities in selecting candidates have been documented in a South Africa despite the availability of guidelines. No data is available on selection outcomes using the current 2010 prioritization guidelines of Western Cape. We audited the outcome of patients assessed for the renal replacement therapy at Groote Schuur hospital.

Methodology. A retrospective analytic study of patients presented to the renal replacement therapy committee was conducted in the renal unit of Groote Schuur Hospital. Outcome letters, proceedings from the committee meetings and the hospital database were sources of data used. All new patients presented between 2008 and 2012 were included in the study. Data entry and statistical analysis was done using SPSS v.22.

Results. A total of 734 ESKD patients were assessed for renal replacement therapy between January, 2008 and December, 2012. During that period, there were 564 new patients, of which more than half (53.9%) were not selected for the program. Following the introduction of the new prioritization criteria a trend towards increasing number of patients presented and accepted was noted. More males were presented (M: F = 1.3) and most patients were below the age of 50yrs (n=478, 84.8%). Half of the patients came from low socioeconomic areas. There were no significant differences in socio-demographic factors before and after introduction of the new guidelines. Clinically they had advanced disease with either uremic (n=181, 44.4%) or fluid overload (n=179, 43.9%) symptoms as their major presentation. The underlying causes were Hypertension (40.6%), Diabetes (14.4%) and chronic Glomerulonephritis (15.8%). Predictors of rejection from the program included age above 50 years, unemployment and a poor psychosocial assessment. Substance abuse and Diabetes also showed a statistical significant association with the likelihood of being rejected. Race and marital status were not predictors.

Conclusion and Recommendations. Efforts to allocate more resources should continue in view of the loss of young and potential productive life. Advanced presentation of patients with ESRD represents challenges in early diagnosis and referral in the current system. Community screening programs and improved access to knowledgeable clinicians at the primary level is advocated. The use of new selection guidelines have not led to an increase in selection inequalities.

1.0 Introduction

The increasing burden of non-communicable diseases worldwide is translating into an epidemic of Chronic Kidney Diseases (CKD).^[1] CKD is increasingly being recognized as a public health problem, as documented by the rising number of patients requiring end stage kidney management.^{[1][2]} As most End Stage Kidney Disease (ESKD) data are obtained in the high income countries, the 7% annual increment^[3] in patients treated for ESKD is likely an underestimation of the global burden.

In developing countries where health systems are already strained by communicable diseases, such ESKD patients are challenged in getting appropriate treatment. Although data on ESKD patients in sub Saharan Africa are inadequate, reports suggest these patients have few options. While their counterparts in developed countries enjoy the benefits of renal dialysis, many patients in sub Saharan Africa die from the effects of uremia.^{[4][5]} Their health systems are constrained by the inadequate resources which include human resources, numbers of renal units, transplantation programs and the high cost of care.^[6]

In the few state sponsored programs, a limited number of treatment slots are usually allocated depending on the budget. This is based on the economical fact that the three ways of working within a budget and containing the costs is either to increase productivity, to decrease quality, or reduce the numbers treated.^[7]

In a setting of resource restriction, selection of patients with the most favorable outcome is desired. Committees which perform these assessments and make weighty decisions are faced with the challenge of denying life prolonging therapy to some patients. To guide such assessment meetings, a set of medical and social criteria have been used to avoid bias. As kidney transplantation has the potential to keep the cost of such programs manageable^[7], all selected patients have to be transplantable.

A similar scenario exists in South Africa where rationing has been in place since the introduction of renal replacement therapy.^[8] The situation in the Western Cape serves as an

example. The provision of dialysis services in this area is inadequate with an estimated shortfall of between 600 to 2000 patients annually.^[9]

In the context of resource constraints, the National department of Health in 1997 introduced dialysis and transplantation guidelines which emphasized on equitable access to treatment for all who require it.^[10]

Despite these guidelines in South Africa, there have been reports of inequality in the selection of patients. The dangers of rationing dialysis were demonstrated in one Western Cape hospital whereby patients likely to be selected were young and white.^[8] Despite these shortfalls it is still recommended to have a national guideline for eligibility of renal replacement therapy as a means of promoting equity in provision of care.^[11]

Amidst objections from some nephrologists^[12], the Department of Health of South Africa updated the guidelines for chronic dialysis in South Africa in 2009.^[13] These guidelines focused more on exclusion criteria and not on a prioritization system. To cater for priority setting, new guidelines have been published in 2010 for rationing dialysis in Western Cape.^[9] Patients are classified into three categories which will determine their allocation of resources (Appendix 1). As an example a category 1 patient will receive treatment regardless of whether the allocated dialysis number is full or not.

Despite these outcome oriented criteria, the unpleasant question of equity still exists 20 years after the apartheid system. This sensitive issue has the potential of attracting negative press to a program.^[11] It is thus desirable to appraise the characteristics of patients accepted to the program in the light of the new guidelines. This work aims at exploring the characteristics and outcomes of patients presented for the chronic renal replacement program at Groote Schuur Hospital.

2.0 Literature Review

2.1 Epidemiology of End Stage Kidney disease

The burden of End stage Kidney disease (ESKD) is increasing globally making Chronic Kidney Disease (CKD) a public health problem worldwide. Even though data is lacking in sub-Saharan Africa ^{[14][15][16]}, the burden of CKD and therefore ESKD is also projected to rise in these developing countries. ^[17] Among other factors, urbanization, infectious diseases like HIV and non-communicable diseases are thought to fuel these projections. High mortality of ESKD patients in sub-Saharan countries is expected due to the inadequate infrastructure and skilled labor. ^[3] Even in some centers where therapy is available, mortality remains high since treatment is unaffordable. As an example, only 6.8% of the ESKD patients survived on Hemodialysis for longer than three months in a Nigerian center. ^[5] In such a scenario, focusing on prevention of CKD is more desirable. Conducting screening activities, early diagnosis and addressing risk factors have thus been recommended. ^[18]

The major risk factors of Chronic Kidney Disease (CKD) in Africa include Hypertension, Glomerulonephritis, HIV infection and Diabetes mellitus. ^[15] Data from the South African renal society reveal a similar pattern among patients receiving dialysis. Hypertension, Diabetes and glomerulonephritis were among the most common reported causes of ESRD. ^[19] In a biopsy series aimed at determining the histological diagnoses of ESKD in Cape Town, the distribution was similar. Among 144 patients biopsied, the causes found were chronic glomerulonephritis was in 31%, Hypertension was in 29.9% and HIV-associated Nephropathy (HIVAN) in 12.5%. ^[4]

These major etiological causes of CKD often present decades before the onset of Kidney diseases. Unfortunately due to poverty, lack of education or poor access to medical care patients presents with advanced kidney disease requiring dialysis. ^{[5][20]} It is thus not surprising as CKD has been associated with poverty. ^[21]

Furthermore, they present at an age when they are expected to be productive members of the society. Most present about a decade younger than those in developed countries. ^{[5][20]} The mean age of dialysis requiring patients is 49yrs in South Africa. ^[19]

So, in the setting of resource limitation these CKD patients are faced with economic challenges in accessing treatment. To highlight the constraints we take for example South Africa, a country with approximately 50 million people is covered with a 2.1 nephrologists per million population as compared with 16 nephrologist per million population in the United States. ^[14] Likewise the number of ESKD patients on renal replacement therapy is comparably less. The number of dialysis units in South Africa's public sector and private sector as of 2012 were 28 and 163 respectively. Collectively these units treated 8,559 patients giving a prevalence of renal replacement therapy of 164 per million population. The public sector is even more resource limited with a lower prevalence of 73 per million population. ^[19] The inequities extend to include marked differences between the public and private sectors. It is estimated that only 12.5% of ESRD patients requiring dialysis in the public sector receive treatment in Western Cape, South Africa. ^[9] Therefore, in countries with state sponsored dialysis programs', rationing of dialysis combined with a transplant program has emerged as the acceptable compromise.

2.2 History of Rationing Dialysis

The origin of the current hemodialysis machine comes from Holland. Invention of the artificial kidney by Willem Kolff in 1944 was later improved by Belding Scribner and others in 1960. ^[22] This represented a new era in treatment of uremia which started in Seattle Artificial Kidney Center at the Swedish Hospital. ^{[23][22]} Due to resource limitations, this lifesaving treatment could only be available to the chosen few. The hospital's Admission and Policy committee selected patients, and the process was twofold. First a panel of nephrologist screened patients who were medically eligible. Patients had to be under the age of 45 years, medically stable and emotionally mature. Other criteria included absence of longstanding hypertension or vascular disease. Secondly, an anonymous committee of six decided on who would be included. ^[23] Social worth was a major consideration in this

'God committee' as it was informally termed. This selection method was highly criticized after being publicized.^[24] Not only was it considered inappropriate but its equity was in question. Patients likely to be selected were middle aged, middle class and white men.^[25] Several other committees^[26] across the United States followed these principles, only a few would use lottery or first come basis as a selection method. Most relied on traits which would ensure adherence to dialysis treatments.^[26]

It was not until 1972 when dialysis became incorporated into Medicare, that widespread availability was a reality in United States.^[27] Despite this widespread availability, a selection criteria consisting of qualitative prognosis, medical benefit, ability to pay and age have been used.^[28]

Once an expensive life-saving treatment becomes available for the first time in a country, rationing is expected. And hence, the practice of rationing in Europe was inevitable. Comparable selection committees were present in Britain. Rationing still continued covertly at a time when it was being abandoned in the United States.^[29]

Similarly in South Africa, rationing has been practiced since the introduction of renal replacement therapy in the country.^[8] Selection of patients during the apartheid era was associated with racial disparities. For 46 years since 1948, the apartheid health policy affected blacks through segregation of health services and unequal expenditure on health services.^[30] Inequalities in distribution of patients on dialysis were thus evident. As an example in the year 1994 the overall treatment acceptance rate in South Africa was 17 patients per million population per year (PPM/yr). And blacks (8.4 PPM/yr) were under represented compared to colored (32 PPM/yr), white (41 PPM/yr), or Asians (97 PPM/yr).^[31] In the new South Africa, the government has aspired to provide equitable access to health care.^{[30][32]}

However, realizing these aspirations has been challenging. The deficit in skilled personnel and insufficient budget allocation has made rationing of dialysis an unavoidable option. Hospital committees have evolved to ensure equity in patients selected onto their dialysis

programs. To guide these committees, criteria consisting of both medical and social aspects have been used and formalized by the government. In the Western Cape, a renal replacement therapy (RRT) committee is composed of at least a nephrologist, social worker and a doctor in charge of the case.^[9] Suitability for kidney transplantation is the main underlying criteria.

Moosa and others looked at the outcome of one Assessment committee in Western Cape.^[8] More than half of 2442 patients assessed between 1988 and 2003 were not accepted for treatment. Those accepted were likely to be below 40 years of age, white, employed, married, non-diabetic and lived in proximity to a dialysis center. Social factors associated with poverty were the main cause of denial of treatment in this hospital. These unfortunate outcomes are similar to those seen in 1960s in the USA.

One could question the criteria in place. Does targeting a transplantable individual lead to inequality in care provision? A review of the guideline would be informative.

2.3 Guidelines for the Renal Replacement Program in South Africa

It is recommended to have a national guideline for eligibility of renal replacement therapy as a means of promoting equity in provision of care.^[11] The National department of Health in 1997 produced dialysis and transplantation guideline which emphasized on equitable access to treatment for all who require it.^[10]

Late in 1997, these guidelines were challenged in the Constitutional Court of South Africa. Mr. Soobramoney was a 41 years old diabetic who was denied dialysis because of advanced vascular disease. According to the guidelines, his advanced vascular disease excluded him from the state funded dialysis and transplantation program in Durban. He based his argument on section 27(3) of the 1996 South African Constitution which states “No one may be refused emergency medical treatment” and section 11 which stipulates “Everyone has the right to life”. The judgment was in favor of the Ministry of Health. Mr. Soobramoney’s medical condition was judged as a chronic and furthermore it was argued that interpretation of section 27(3) should be made in the context of 27(1) and 27(2). These

outline the state's obligation to provide health care services to all. And in 27(2), it is stipulated that these provisions are limited by the available resources, given the high cost of dialysis.^[32] The ruling, in addition acknowledged the use of guidelines in selection of candidates. In this manner it strengthened the legal basis of the document.^[33]

In 2009 the department of health updated the guidelines for chronic dialysis in South Africa.^[13] These guidelines had more exclusion criteria and allowed stable HIV positive patients to be included in the chronic dialysis programs.

Current guidelines in Western Cape were published in 2010 for rationing chronic dialysis.^[9] Under these new guidelines the basis of selection includes the following three elements as described in the guideline.^[9] 'Firstly, all patients accepted for renal replacement therapy must therefore be eventually suitable for transplantation. Secondly, the allocation of the scarce resource must be done in such a way as to maximize the benefit that the society will eventually derive from such an allocation (utilitarianism). Thirdly, once transplanted, patients should be capable of reliably taking care of themselves and their grafts to ensure the optimal survival of the organ.'

Both the abovementioned elements have strong socio-economic connotations. So despite the earlier reports of inequality, the new guideline will most likely continue to marginalize the socioeconomically disadvantaged population. Utilitarianism ensures maximum benefit from the candidate selected. Meaning if transplanted, the candidate will survive the longest. Equity means everyone who benefits from therapy should have comparable chance to receive it. Unfortunately utilitarianism and equity are opposing principles.^[34] So by design, these guidelines will suffer in equity. Which means not everyone who benefits from the renal replacement therapy will have a comparable opportunity. These unfortunately, are the realities of resource limitation.

The positive side of these new guidelines is the introduction of a prioritization policy (Appendix 1) which should theoretically increase the number of treated patients. Patients are classified into three categories which will determine the allocation of resources. As an example a category 1 patient will receive treatment regardless of whether the allocated dialysis number is full or not. To qualify as a category 1 patient one has to be less than 50 years with a body mass index of less than 30kg/m² and have no category 2 criteria. Category 2 criteria include conditions that reduce the candidate's suitability for transplant eg. Diabetes, Hypertension with severe target organ damage, stable HIV and hepatitis infection and others as outlined in Appendix 1. These category 2 patients will be offered treatment when resources are available. And a category 3 patient will be offered conservative therapy. Category 3 candidates are unlikely to benefit from Kidney transplantation due to unacceptable mortality and morbidity risk.

In comparison with the guidelines before 2010 (Table 1), one should hypothetically be able to predict the outcome of patients presented. The introduction of new guidelines on one hand narrows the eligible population by placing an age restriction particularly in diabetics, on the other hand, prioritization policy could increase the number of patients treated. In Groote Schuur, the latter is more likely to be true. This is because the guidelines used in Groote Schuur Renal Replacement Therapy (RRT) committee resemble the new Western Cape guidelines. In 2008 the Groote Schuur RRT committee developed an assessment tool^[4] which later evolved into the current categorization criteria (Appendix 4).

Table 1: Comparison of Western Cape Guidelines (2010) with the Department of Health Guidelines (2009).

Aspect	Western Cape Guidelines ^[9] , 2010	Department of Health Guidelines ^[13] , before 2010
Principles	Patients must be suitable for transplantation	Transplantation a major criterion
	Guide on modality of chronic dialysis not stated.	Patient and family should be allowed to choose the modality of chronic dialysis
Selection criteria	Both inclusion and exclusion criteria used for selection	Exclusion rather than inclusion criteria applied for selection
Medical	Medical exclusion criteria include active malignancy and advanced irreversible progressive disease of vital organs	Medical exclusion criteria include active malignancy and advanced irreversible progressive disease of vital organs
	Diabetes will be considered below the age of 50years. Comorbid diseases may be considered.	Diabetes and acceptable comorbidity may be considered
	Hepatitis B e Antigen positivity to be excluded	Hepatitis B e Antigen <u>Not</u> specified
	Morbid obesity BMI>35 to be excluded	BMI limits not specified
	Age above 60yrs are excluded	No age limit stated
Psychosocial	Mental illness with diminished functional capacity as shown by psychiatric and medical examination.	Mental illness with diminished functional capacity
	Habitual non adherence with any medical treatment	Habitual non-compliance with dialysis treatment and lifestyle modification.

Evidence for the Selection Criteria

The cost of dialysis in South Africa is high and hence limited slots are available in state sponsored programs. Therefore selection of patients for the renal replacement therapy should be based on predicting outcomes after transplantation. The factors that are known to be associated with survival after transplantation are diverse and include social and medical aspects.

Socio-demographics and economic factors

Older age has been associated with decreased survival rates after kidney transplantation.

There is a significant decline in survival after the age of 60 years.^[35] As an example, the 5-year survival of a non-diabetic candidate aged 56 years is 86% versus 81% if 61yrs receiving a cadaveric kidney transplant.^[36] However data from South Africa suggests 40 years as the age which demonstrated the most striking difference in survival.^[37]

Several investigators have reported racial disparities in patient survival, whereby it was noted that the black population had a poorer survival rate compared to non-black

population.^{[38][39][35]} According to the United States organ procurement and transplantation data, the 5 year survival of blacks is 61% compared to 74% among whites.^[40] Such disparities may be explained by immunological differences or by socioeconomic differences.^[35]

However, racial differences in transplant survival tend to disappear when controlled for socioeconomic status.^{[41] [42]} This fact becomes obvious in the South African setting where race was not found to be a determinant in transplant survival.^[37] As the selection guideline in South Africa ensures a minimum acceptable socioeconomic status, racial differences attributed to socioeconomic factors will likely be insignificant.

Another social criterion considered is substance abuse. Active substance use or dependency is used as a strict exclusion criterion. Poor treatment compliance, infection risk and continued organ damage have been cited as reasons for unfavorable transplant outcomes. The KDIGO guideline^[43] is silent about substance abuse, however data from the US demonstrates a significant increased risk of graft loss.^[44]

Comorbid diseases including Diabetes Mellitus

Medical factors which predict good outcomes are plausible and also evidence based. Data from the Canadian Organ Replacement Registry^[36] showed that increased comorbidity was strongly associated with reduced patient survival. Comorbid diseases used in this registry included coronary artery disease, congestive cardiac failure, cerebrovascular accident, peripheral vascular disease, dementia and chronic obstructive lung disease. Another disease included in the score was Diabetes mellitus. This Canadian registry does justify the current criteria of excluding diabetics above the age of 50 years by developing survival tables in diabetics and non-diabetics. The 5 year survival of diabetics aged between 50 and 59 years ranged from 79% to 85% compared to non-diabetics which were from 86% to 90%.^[36] The basis for this excess higher mortality in diabetic patients relates with sepsis and cardiovascular mortality in the transplanted patient.

Obesity and cardiovascular risk in transplantation

Kidney transplant recipients are at an increased cardiovascular risk^[45] due to the associated immunosuppression exposure, new onset diabetes and a chronic inflammatory state.^[46]

Obesity has also been associated with increased delayed graft function and short-term mortality.^[47] It would hence be reasonable to accept patients with reduced cardiovascular risk to begin with. Therefore, the guidelines require all patients to have a BMI of 35kg/m² and below. Patients below 30kg/m² would be considered for the category one status.

The measurement of waist circumference has been demonstrated to predict atherogenesis more accurately. Furthermore there is evidence to suggest that waist circumference (a measure of visceral obesity) predicts post-transplant outcomes better than BMI.^[47]

Smoking

Smoking is preventable cause of morbidity and mortality. Although the mechanism of kidney damage is not entirely clear, it has been associated with hypertension, diabetes and hence a major cardiovascular risk. Data from the United States illustrate the increased mortality (hazard ratio of 2.32) of smoking after transplantation.^[48]

Human Immunodeficiency Virus

Another condition which causes a high mortality and morbidity in South Africa is HIV/AIDS.

Over the past decade the survival of HIV positive patients has improved. Although there has been a decrease in the traditional causes of death from AIDS, an increase in mortality from non-communicable diseases in HIV has been observed. HIV associated nephropathy is now an important cause ESRD in South Africa.^[15] In a biopsy series from Cape Town, HIV increased from 6.6% in 2000 to 25% in 2009.^[49] Before 2008, patients with ESRD due to HIV were not being accepted onto the renal replacement program^{[50][51]} because there was no data on their survival outcomes with transplantation. However, it was later shown that patients with stable HIV disease had similar renal transplant outcomes as HIV negative patients.^{[52][53][54][51]} Currently, HIV is no longer considered as a contraindication for kidney transplantation^[55] as long as patients have controlled disease. Eligible patients are those with a CD4+ T cell count above 200/ml, have an undetectable viral load and, if on

antiretroviral (ARV) treatment, have demonstrated good adherence and clinical response within 6 months prior to assessment. In 2009 the South African department of health issued guidelines which accepted stable HIV positive patients onto the renal replacement therapy program.^[13]

Hepatitis Virus

The program requires patients who have hepatitis be free from cirrhosis and be on treatment. This stems from data showing increased mortality in untreated patients. Data from France looking at 1238 kidney transplant patients for 10 years demonstrates clearly an increased mortality in patients infected with either hepatitis B or C.^[56]

Habitual Non-adherence with any medical treatment

Compliance to treatment is paramount to the survival of the graft because of the associated rejection risk.^[43] History of non-compliance is used as an exclusion criterion for acceptance onto the Western Cape program. Pre-transplant non-adherence has been shown to predict post-transplant non-adherence with an odds ratio of 7.9.^[57]

3.0 Rationale

Treatment of end stage kidney disease carries a huge economic burden even in developed countries. In emerging economies like South Africa with a gross domestic product per capita of 6,617 USD, dialysis is expensive. Unsubsidized patients in the South African state sector would pay about 16,000 USD/year and 17,000 USD/year in private. So in states with programs which have limited treatment spaces, rationing of dialysis is inevitable. In South Africa, guidelines in rationing dialysis are necessary to enable hospitals to select the most appropriate candidates. New guidelines were produced by the Western Cape in 2010. This audit documents the outcome of rationing dialysis in the light of the new guidelines. In this documentation marginalization of certain patient groups was also assessed. Information obtained should help in strengthening the current guideline. Comparing data derived from the era prior to the implementation of these guidelines has helped appraise their fairness. This work has also shed light on the need for policy makers to allocate resources to the care of ESKD.

4.0 Study Aims and Objectives

Broad objective

To assess the outcomes of patients presented to the renal replacement committee at Groote Schuur Hospital.

Specific objectives

1. To describe the socio-demographic characteristics of patients presented
2. To describe the clinical characteristics of patients presented
3. To determine the factors associated with selection of patients onto the program
4. To compare the characteristics of patients selected before and after implementation of the current guidelines

5.0 Research Design and Methodology

5.1 Study Design.

This was a retrospective analytic study in which characteristics and outcomes of patients assessed by the renal replacement therapy (RRT) committee were recorded from the assessment letters.

5.2 Study population

All new patients presented to the Renal Replacement Therapy Committee at the Groote Schuur Hospital from January 1st, 2008 to December 31st, 2012 were included in the audit. Groote Schuur is a state owned and tertiary hospital serving half of the Western Cape Province. The catchment population consists of a wide range of socio-economic and ethnic groups. In 2011, the population in the city of Cape Town was 3.7 million.^[58] Of these, females were 51% and the ethnic distribution was as follows Blacks 38.6%, Colored 42.4%, Asians 1.4%, Whites 15.7% and others were 1.9%.

5.2.1 Exclusion criteria

Excluded from this audit were patients presented for modality change, patients presented for transplantation only (Patients accepted for renal replacement therapy elsewhere) and patients after transplantation. Other patients excluded were re-assessments and appeals.

5.3 Assessment of patients for the Renal Replacement Program

The RRT committee convened every Thursday at the renal department of Groote Schuur. The composition of a RRT committee included the doctor taking care of the patient, social worker and at least 2 Nephrologists. Others included may be the responsible medical superintendent or representative, renal unit staff representative and anybody else invited by the Chair (6). The Department has an allocation of 148 (plus 5 Hepatitis B positive patients) slots for treating ESKD patients.

The assessment of eligibility for the renal replacement program was based on the information made available to the committee. Patients were presented by the doctor and social worker taking care of the patient. The outcome from the RRT committee included firstly, the patients' category and secondly, whether the patient is accepted to start dialysis immediately.

Patients were classified into three categories based on criteria described in Appendix 2. After introduction of the prioritization guidelines in 2010, the following prioritization categories were used to judge acceptance onto the program. Category 1 patients must be accommodated on the dialysis and transplant program. Resources will always be found to treat these patients. Category 2 patients will be accommodated on the program only if resources allow, with priority given to the category 2 patients waiting the longest and those who have the best chance of good outcomes. Category 3 patients will be offered optimal conservative treatment and will not be offered renal replacement therapy.

Before 2010, patients were accepted onto the renal replacement program based on their transplantability and no prioritization was made. Nevertheless, from 2008 to 2009 patients were classified into 3 categories based on a locally developed assessment tool (Appendix 4).^[14] This earlier version was more comprehensive in terms of the social factors and hence not comparable with the new system. To be able to compare the period before and after introduction of the new guidelines, the principal investigator classified all new patients presented before introduction of the new guidelines. This means that the same criteria to categorize patients were used in all periods (Appendix 2) using the 2010 criteria.

Each candidate presented to the RRT committee had an assessment letter prepared by a nephrologist present during the assessment. This letter also contained a summary of the psychosocial assessment made by the social worker (Appendix 5).

5.4 Data Collection and Management

Patient's characteristics and the outcome of the RRT committee were summarized into a case record form (Appendix 1). This information was derived from the outcome letter and psychosocial assessments produced. These letters were available in the department. Additional information was obtained from the proceedings recorded during the meeting. Some of the socio-demographic information was obtained from Groote Schuur Hospital Clinicom database (Appendix 3). Being accepted as a category 2 patient does not guarantee RRT. Information on category 2 patients who eventually got onto the program was obtained from the HLA antibody list provided by the National Health Laboratory Services.

The variables included in the Case Record Form were demographic data which included age, sex, marital and employment status. Others were race, residence and religion. Clinical data collected were the major presenting complaint, body mass index and serology for HIV/Hepatitis B surface antigen. Other clinical data recorded were the underlying renal diagnosis, co-morbidities and whether the patient required dialysis (late referral). The psychosocial data included the assessment of the home conditions, social support and insight. History of noncompliance to treatment and history of substance abuse were also noted. Outcome variables recorded into the case record form were category of the patient and whether the patient was accepted onto the program.

The data from the case record form was then entered into Statistical Package for Social Sciences (SPSS) v22.0.0.0.

5.5 Definition of terms (operational definitions)

1. **Non-blacks race** included whites, Asians and mixed race.

2. **Ever married** included married, divorced and widowed
3. **Employed** was any candidate who works. This could be self-employment, informal or formal employment.
4. **Dependents** were any person who relied on the candidates support for daily living.
5. **Overall psychosocial assessment.** A good candidate was one whose psychosocial report summary (Appendix 5) by the social worker was positive and deemed fit for the program. If the social worker was unable to decide or classified a candidate as unfit for the program, the candidate was categorized as Poor
6. **Non-compliance** any lack of adherence to appointments or medication.
7. **Substance abuse.** Use of any highly addictive substance excluding nicotine. In the case of alcohol, excessive use/dependency had to be demonstrated.
8. **Hospital Care Cost.** GSH classifies patients according to their ability to pay the hospital bills.^[59] H0 are pensioners, those on grants and formally unemployed. H1 are those who earn up to 36,000 rands per annum. H2 those who earn 36,000-72,000 per annum. H3 above 72,000 rands per annum. Patients classified as Private were those charged full patient fees with no subsidized prices. Charged patients comprised H1,H2, and H3 patients. In this research protocol patients were classified as paying patients or non-paying patients
9. **Socio economic status in the Cape Town area.** The socioeconomic status of areas in Cape Town was mapped in 2001.^[60] A socioeconomic status index was based on low income, low educational attainment, high unemployment levels and jobs in

relatively unskilled occupations. Patients' area codes were used to classify patients as either coming from an area with the worse 20% socioeconomic status index or not.

10. **Renal diagnoses.** A number of comorbidities/underlying diagnoses were noted.

These included Hypertension, Chronic glomerulonephritis, Diabetic nephropathy, HIVAN, Urological causes, Cystic Kidney disease and interstitial nephritis. Definition of these relied on the records as noted by the doctor completing the assessment letter.

5.6 Data analysis and statistical considerations

Before data analysis was attempted, the complete data set was checked for errors. This was done by two methods. Firstly, by manually comparing the data with the meeting proceedings books, the data was checked for accuracy. Secondly, each variable was re-checked for errors using descriptive statistics and scatterplots in SPSS. Missing cases were noted for some variables. These were excluded in the respective analysis.

The clean dataset in SPSS was summarized into cross tables and bar charts to describe the study population. The population was described in three separate time periods. The first period was 2008 to 2009 in which no prioritization guidelines were used. In 2010 new guidelines were being introduced, some patients were still assessed using the old guidelines. The third period was from 2011 to 2012 where the new guidelines were used consistently.

Univariate analysis was performed to assess factors associated with acceptance onto the RRT program. Chi square and odd ratios were calculated. The factors which were found to be significant were then assessed using logistic regression (multivariate analysis). In both instances (univariate and multivariate analysis), a p-value of less than 0.05 was considered as significant.

In addition, residences were coded based on the patients' postal code as obtained from Groote Schuur Clinicom database. This was then geo-coded using a google geo-coding website. This means the latitudes and longitudes were obtained using google. These Geo-data were then used to develop a map illustrating the distribution of new patients assessed by the renal assessment committee.

5.7 Ethical considerations

The conduct of this work followed the ethical principles from the World Medical Association Declaration of Helsinki.^[61] In its retrospective design this audit confers no direct risks, burdens or benefits to the patients. Privacy and confidentiality of the subjects were protected. The patients' identity was hidden by use of a code instead of names in the case record form. Furthermore the case record forms are stored in the investigators office. Data entered is password protected.

Informed consent will not be sought as this is a retrospective audit. And also lack of informed consent is justified by the fact that the investigators are part of the therapeutic team. The data are not accessed by a third party and hence not a breach of confidentiality. Furthermore, it is the obligation of the therapeutic team to ensure justice in the selection of patients into the renal replacement program is assured. Hence this audit represents the exception in the requirement of informed consent in retrospective studies as described by Junod and Elga.^[62]

Finally this protocol has ethical approval from the Faculty of Health sciences, Human Research Ethics Committee of the University of Cape Town (HREC REF: 085/2013).

6.0 Results

Assessment statistics

Between January 1st, 2008 and December 31st, 2012 there were 734 patients who were assessed for the Groote Schuur Hospital renal replacement program (Figure 1). The trend has been of increasing number of patients brought to the assessment meetings over the 5 years of observation (Figure 2). Overall, 564 patients were new assessments (Figure 1) and the trend was towards an increase (Figure 3) in the absolute number of patients accepted ($p=0.025$, $\chi^2 = 11.15$). However the number of transplants performed has declined over the period of observation (Figure 4). In 2009 there was an increase in transplant which corresponded with an increase in the number of accepted patients.

Figure 1: Flow chart of patients assessed for the renal replacement therapy in Groote Schuur Hospital 2008-2012.

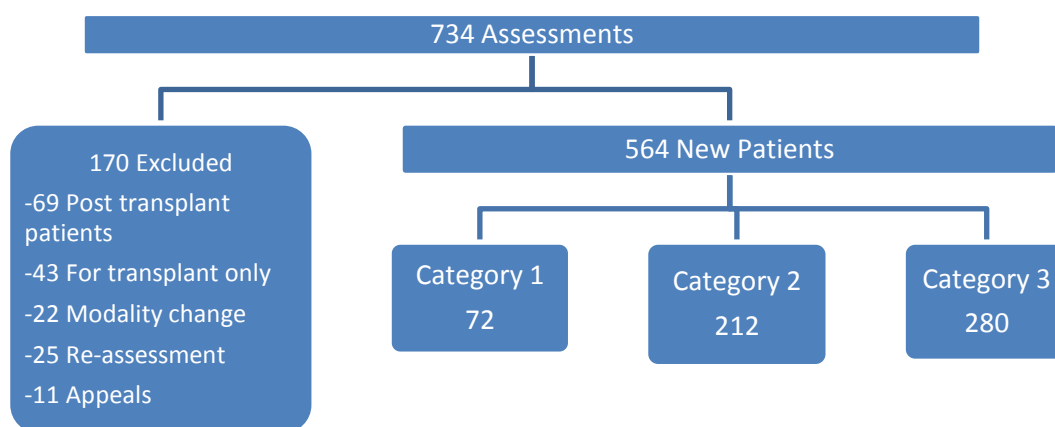


Figure 2: Graph showing the distribution of patients' categories according to the year presented among all patients (N=712).

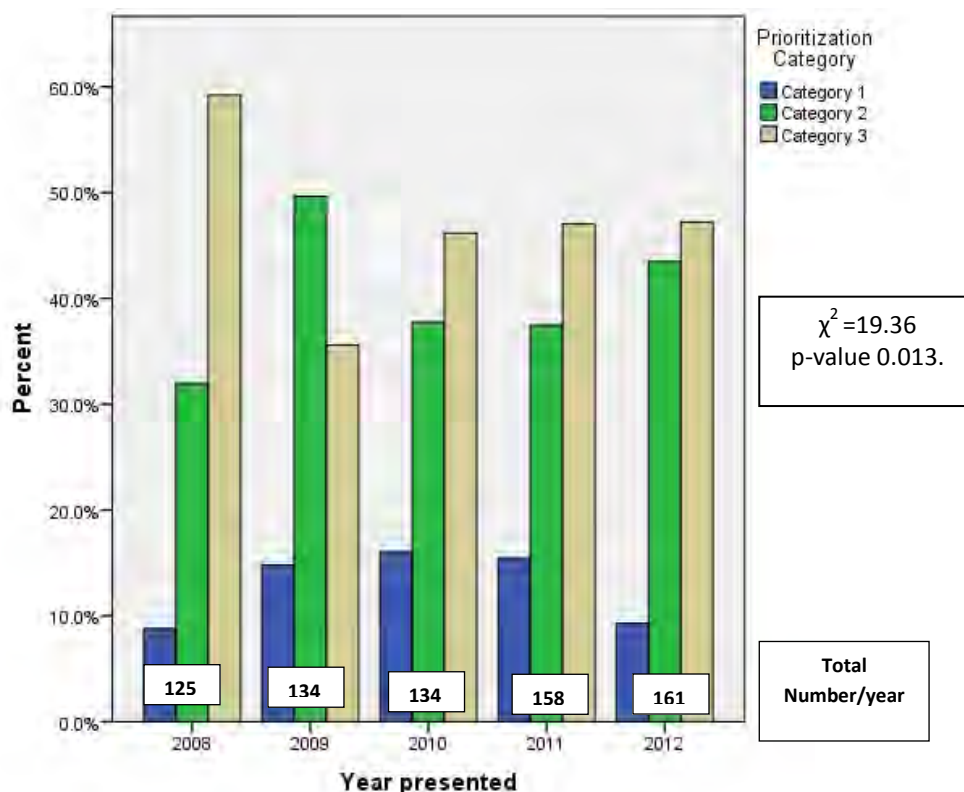


Figure 3: A graph showing the distribution of new patients' outcomes according to the year presented (N=564).

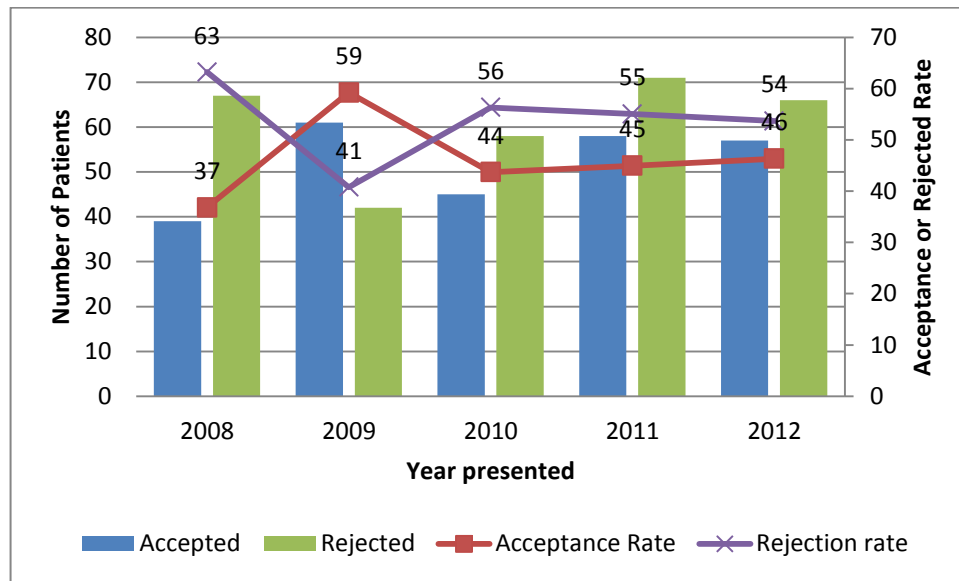
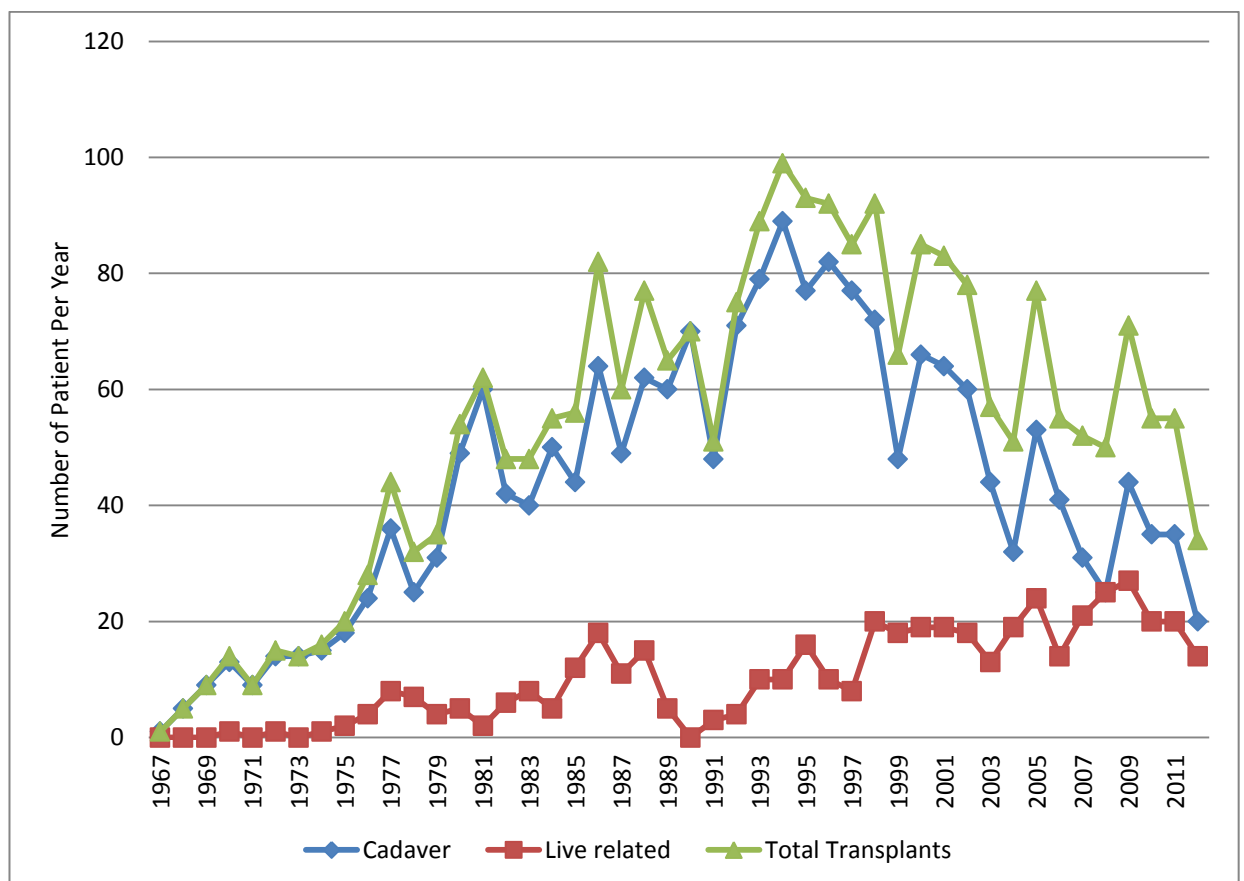


Figure 4: A Graph showing the number of patients who had kidney transplantation at Groote Schuur Hospital from 1990-2012.



Socio-demographic characteristics of the assessed patients

The cohort of new patients assessed was composed of fewer blacks compared to non-blacks (43.1% vs 56.9%) and more males were presented (male to female ratio of 1.3). The median age of patients presented was 40yrs with range between 13yrs and 60yrs. Mean of 39.1. The majority were below the age of 50yrs (n=478, 84.8%). Most patients presented were South Africans (n=543, 96.3%) with dependents (n=346, 67.3%).

The presented patients were mostly assessed as compliant (n=425, 78.4%) with no history of substance abuse (n=453, 83.6%). The most common substance abused was ethanol followed by cannabis.

Even though most were classified as paying patients (n=433, 93.7%), half came from low socioeconomic areas (the worse 20% in Cape Town). Overall, there were no significant differences in socio-demographic factors before and after introduction of the new guidelines (Table 2).

Table 2: Socio-demographic characteristics of new patients presented to the renal assessment committee in Groote Schuur from 2008-2012.

Variable	Presentation periods			χ^2	p-value*
	2008-2009 N (%)	2010 N (%)	2011-2012 N (%)		
Male gender	116(55.5)	64(62.1)	138(54.8)	1.72	0.42
Blacks race	84(40.2)	44(42.7)	115(45.6)	1.38	0.50
Age below 50 years	179(85.6)	88(85.4)	211(83.7)	0.37	0.83
Mean age (years \pm SD)	38.4 \pm 10.5	39.8 \pm 10.1	39.3 \pm 10.8		
Ever married	113(55.4)	54(55.1)	121(52.2)	0.52	0.77
Unemployed	94(45.4)	51(51.0)	119(51.3)	1.72	0.42
Foreign nationality	11(5.3)	3(2.9)	7(2.8)	2.2	0.33
Has Dependents	128(65.6)	69(71.1)	149(67.1)	0.90	0.64
Overall poor psychosocial assessment	90(45.0)	43(43.9)	123(51.7)	2.67	0.26
Non-compliance	37(18.1)	20(20.0)	60(25.2)	3.43	0.18
Substance Abuse	35(17.2)	19(19.0)	35(14.7)	1.08	0.58
Paying patients	162(92.0)	80(93.0)	191(95.5)	1.99	0.37
Worse 20% socioeconomic area in Cape Town	85(46.4)	48(54.5)	109(54)	2.7	0.27

*The χ^2 and p-value are comparing the time periods. All numbers are patient count unless indicated. SD standard deviation

Clinical characteristics of assessed patients

Most patients were symptomatic with either symptoms of uremia (N=181, 44.4%) or fluid overload (N=179, 43.9%) as their major presentation (Table 3). Despite being symptomatic, only 20% (N=116) required emergency dialysis. The median serum creatinine concentration was 1005.5 μ mol/L with standard deviation of 674.

The majority of patients had a BMI below 30kg/m² (N=441, 83.8%) with a median of 24.3 and a range of 31 (14-45kg/m²). Most tested negative for Hepatitis B surface antigen (N=538, 95.4%) and HIV (N=214, 84.9%).

The three presentation periods were clinically comparable in terms of the presentation, body mass index, hepatitis B status, emergency dialysis and presence of comorbid diseases. However HIV positive patients significantly increased after introduction of the new guidelines.

Most of the new patients presented with Hypertension (40.6%), Diabetes (14.4%) or chronic Glomerulonephritis (15.8%) as their underlying cause of End Stage Kidney disease

(Figure 5). In a significant proportion (15.4%), no underlying etiology was found. HIVAN represented a small proportion 3.5% of the presented patients. Patients with Diabetes (Figure 6) were less likely to be accepted (9.2% vs 18.8%) while patients with Chronic glomerulonephritis were more likely to be accepted (20%vs12.2%). This difference was statistically significant ($p=0.008$).

Table 3: Clinical characteristics of new patients presented for the renal replacement program in Groote Schuur hospital from 2008-2012.

Variable(N**)		Presentation periods			χ^2	p-value*
		2008-2009 N (%)	2010 N (%)	2011-2012 N(%)		
Major presentation (408)	Uremic	90(46.9)	31(43.7)	60(41.4)	8.5	0.198
	Fluid overload	73(38.0)	35(49.3)	71(49.0)		
Body mass index (526)	> 30kg/m ²	36(18.2)	18(18.2)	198(13.5)	2.1	0.357
HIV status (564)	Positive	8(3.8)	11(10.7)	38(15.1)	16	<0.001
Hepatitis B surface antigen (564)	Positive	6(2.9)	7(6.8)	13(5.2)	2.7	0.255
Emergency dialysis required (563)	Yes	45(21.6)	20(19.4)	51(20.2)	0.2	0.885
Renal Disease (564)	Diabetes	30(14.4)	15(14.3)	36(14.3)	0.01	0.998
Number of comorbid diseases (564)	None	132(63.2)	65(63.1)	154(61.1)	3.87	0.694
	1	65(31.1)	32(31.1)	75(29.8)		
	2	9(4.3)	4(3.9)	20(7.9)		
	3	3(1.4)	2(1.9)	3(1.2)		

*The χ^2 and p-value are comparing the time periods. All numbers are patient count unless indicated

**The number cases available for the respective variable.

Figure 5: Distribution of main diagnoses of new patients presented to the Renal Replacement Program in Groote Schuur Hospital from 2008-2012. (n=560)

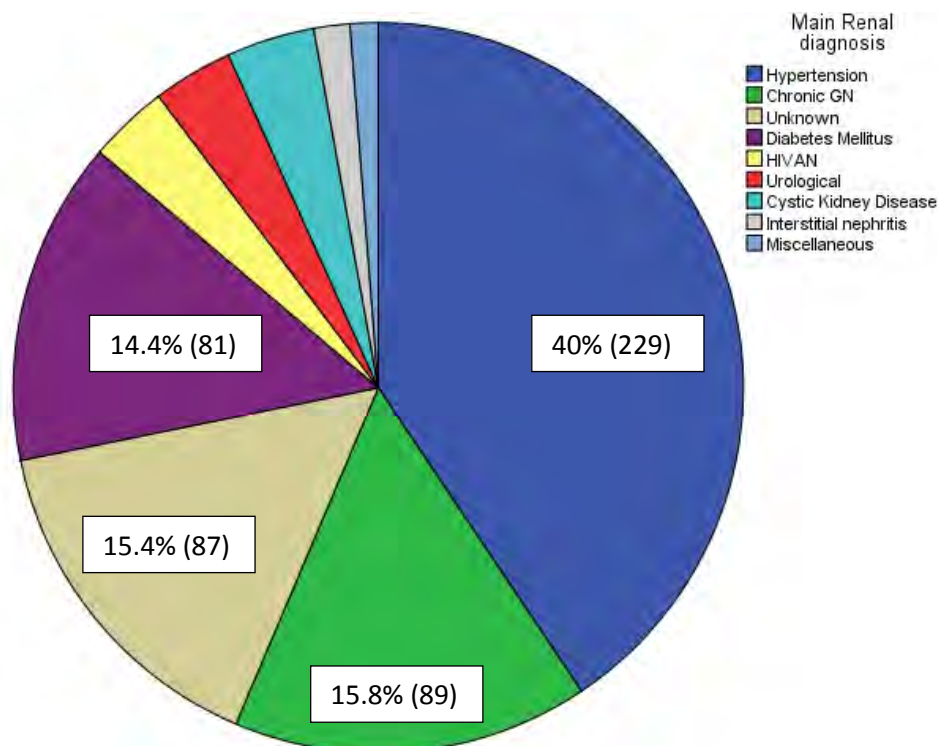
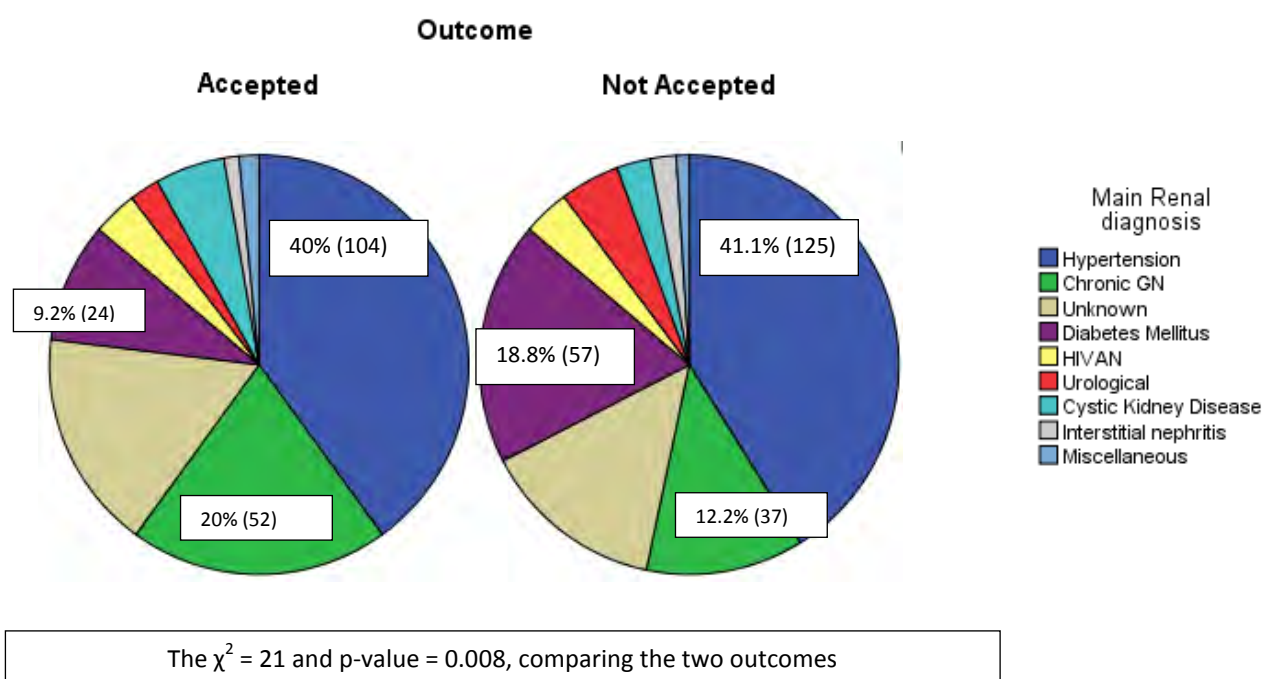


Figure 6: Comparison of the main renal diagnosis according to the outcome of new patients presented for the Renal Replacement Program in Groote Schuur Hospital from 2008-2012.



Predicting acceptance into the renal replacement program

In univariate analysis (Table 4), patients who were black, below 50 years of age and employed were found to have a statistically significant association with being accepted into the renal replacement program. Other predictors included having dependents, a good psychosocial assessment and compliance to treatment. The gender, marital status, nationality, socio-economic area and religion were not associated with acceptance into the program. Although not statistically significant, there was a tendency of selecting patients who can pay (52% vs 34%, $p=0.068$)

Diabetes and presence of comorbid diseases had a statistically significant association with being rejected by the renal replacement committee. Higher serum creatinine levels, hepatitis B positivity, HIV positivity and emergency dialysis at presentation were not statistically associated with rejection into the renal replacement program.

However in the multivariate analysis (Table 5), race, compliance to treatment, dependents, paying patients and comorbid diseases were no longer predictors. So after multivariate analysis, predictors were age above 50 years, unemployment, poor psychosocial assessment, substance abuse and diabetic patients. These showed statistical significant association with being rejected from the renal replacement program.

Table 4: Univariate analysis of predictors of acceptance into the Renal Replacement Program among patients presented in Groote Schuur Hospital from 2008-2012.

	Accepted N (%)	Rejected N (%)	χ^2	p-value*
Socio-demographic predictors				
Male Gender	144(45.3)	174(54.7)	0.20	0.658
Black Race	129(53.1)	114(46.9)	8.39	0.004
Age below 50	233(48.7)	245(51.3)	8.83	0.003
Ever married	147(51.0)	141(49.0)	2.13	0.145
Employed	176(64.0)	99(36.0)	59.9	<0.001
Foreign Nationality	13(61.9)	8(38.1)	2.1	0.139
Has dependents	177(51.2)	169(48.8)	4.0	0.043
Poor Psychosocial assessment	48(18.8)	208(81.3)	165	<0.001
Non-compliant	21(17.9)	96(82.1)	51.9	<0.001
Substance abuse	15(16.9)	74(83.1)	39.4	<0.001
Paying patients	225(52.0)	208(48.0)	3.3	0.068
Worse 20% Socio-economic area	128(52.9)	114(47.1)	1.3	0.252
Clinical predictors				
Uremic encephalopathy	85(47.0)	96(53.0)	1.5	0.681
Diabetes Nephropathy	24(29.6)	57(70.4)	10.30	0.001
Serum Creatinine Above 1001 micromoles/L	128(44.4)	160(55.6)	1.2	0.55
Body Mass Index Above 30	34(40.0)	51(60.0)	3.10	0.074
No comorbid disease	191(54.4)	160(45.6)	27.00	<0.001
Positive Hepatitis B surface antigen	13(50.0)	13(50.0)	0.17	0.683
HIV Positive	21(36.8)	36(63.2)	2.19	0.139
Emergency dialysis required	58(50.0)	58(50.0)	0.894	0.344

*The χ^2 and p-value evaluates the two outcomes.

Table 5: Multivariate analysis of predictors of acceptance by the Renal Replacement committee among new patients presented in Groote Schuur Hospital from 2008-2012.

Predictor	B	Wald χ^2	P	Odds Ratio	95% Confidence Interval	
Black Race	0.114	0.171	0.679	1.121	0.653	1.925
Age above 50yrs	-1.367	10.398	0.001	0.255	0.111	0.585
Unemployment	-1.171	19.375	<0.001	0.310	0.184	0.522
Lack of Dependents	-0.161	0.334	0.563	0.851	0.494	1.469
Poor Psychosocial Assessment	-2.066	49.232	<0.001	0.127	0.071	0.226
Compliance History	0.625	2.911	0.088	1.868	0.911	3.827
Substance Abuse	-1.755	19.334	<0.001	0.173	0.079	0.378
Paying patient	0.155	0.069	0.793	1.167	0.368	3.705
Diabetic Patients	-0.989	5.839	0.016	0.372	0.167	0.830
Comorbid Disease/s	-0.359	1.585	0.208	0.699	0.400	1.221

Effect of prioritization criteria

The introduction of prioritization criteria has not led to changes in outcomes of the assessments. The committee remained consistent in classifying patients (Table 6) in that there was no difference in the proportion of patients classified as either category 1, 2 or 3 after the use of prioritization criteria ($p=0.98$). Before the new criteria, only 2 category 1 patients did not receive renal support (Figure 7). The number of unsupported category 2 patients is higher (22 patients). In overall, even if accepted, almost one third 27.4% (58/212) of category two patients did not get onto the program (Figure 8). The prioritization criteria did not increase the proportion of category 2 patients who joined the program ($p=0.5$). In totality, although the absolute number of patients accepted increased (Figure 7), no change in the proportion of patients who were accepted was noted ($p=0.77$).

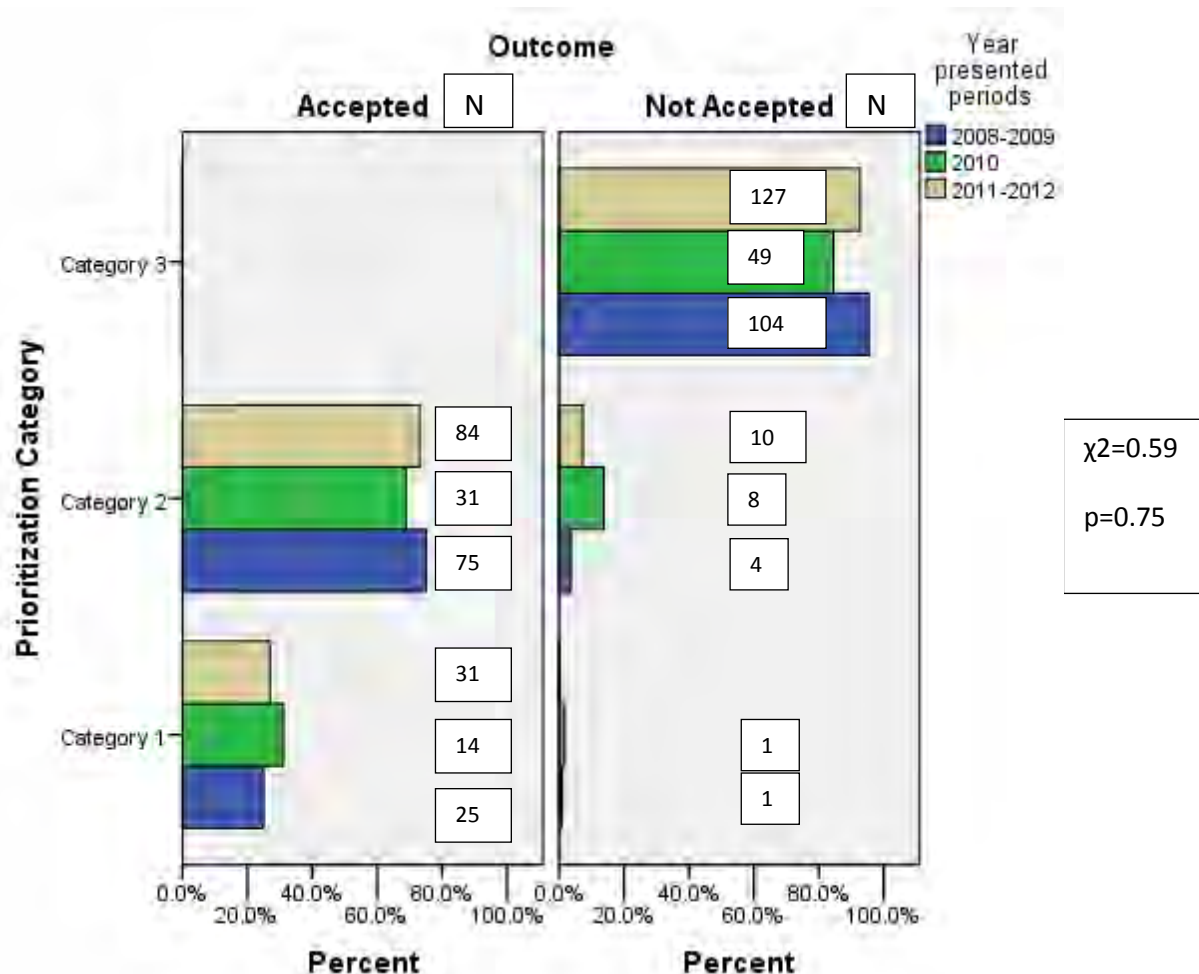
It is noteworthy that there were more HIV positive patients accepted into the programme after introduction of the prioritization criteria (2%vs13.9%, $p=0.006$). All other socio-demographic and clinical variables did not reveal any statistical significant differences between the assessment periods.

Table 6: Characteristics of Patients assessed by the renal replacement committee before and after the use of Prioritization Criteria (N=564).

Variable	Presentation periods			χ^2	p-value
	2008-2009 N (%)	2010 N (%)	2011-2012 N (%)		
Category 1	26(12.4)	15(14.6)	31(12.3)	0.45	0.98
Category 2	79(37.8)	39(37.9)	94(37.3)		
Category 3	104(49.8)	49(47.6)	127(50.4)		
Accepted patients	100(47.8)	45(43.7)	115(45.6)	0.52	0.77
Accepted HIV Positive	8(3.8)	11(10.7)	38(15.1)	15.97	<0.001

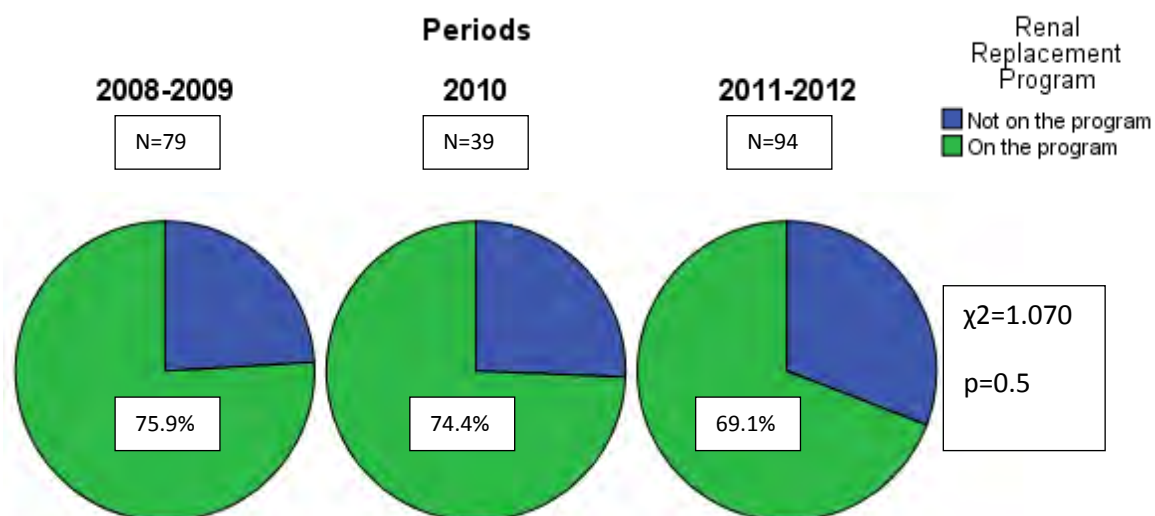
*The χ^2 and p-value evaluate the presentation periods.

Figure 7: Bar chart showing the proportion of patients presented in each assessment periods according to prioritization category (N=564).



Bar chart showing the proportion of patients presented in each assessment periods according to prioritization category (N=564).

Figure 8: Pie charts showing the proportion of category 2 patients on the Transplant list (n=212).



7.0 Discussion

This audit describes the outcome of patients assessed for the Renal Replacement Therapy (RRT) program and explores the extent to which equity in selection of patients onto the program is achieved. A total of 564 new patients were presented to the RRT committee between 2008 and 2012. The average presented patient profiles a potential productive South African citizen i.e. 40yrs male with dependents and classified as able to pay subsidized hospital bills (Table 3). Noting that over half (N=304, 53.9%) were rejected by the committee, this represents in addition, a significant economic loss to the families and South Africa as a whole. These findings seem, at first instance, to negate the principle of utilitarianism. This refers to maximizing the benefit that the society will get from allocation of treatment. Utilitarianism is a criterion for selection of patients according to the current guideline.^[9] However reference is made to transplantation rather than to dialysis treatment in these guidelines. The patients turned down had less favorable characteristics for kidney transplantation. This is unfortunately the cost of maintaining a RRT program in a resource limited setting.

The high cost of renal replacement therapy^[63] combined with the rising burden of chronic kidney disease^{[2][14]} has placed a strain on health systems globally. In Africa, the unmet need for managing ESKD is likely underestimated due to the obvious lack of data.^[63] In countries with well-established government funded programs like South Africa, only about 12.5% of the dialysis need is met.^[9] The success of the dialysis program in South Africa also stems from incorporating transplantation as a pre-requisite for treating patients.

One may predict with confidence that such a deficit in the dialysis slots available, is going to increase. The population in South Africa's increased by 10 million in 18 years yet there was an addition of only 2 dialysis units in the public sector.^[19] In this audit the number of new patients presented to the Groote Schuur Renal Replacement Committee between 2008 and 2012 increased (Figure 2, 3 and 4). This, coupled by a decrease in the number of transplants (Figure 5) will continue to place strain on the available dialysis slots. And during this period only 46% (N=260) of 564 patients could be accepted onto the program (Table 2). A similar proportion of patients (47%) were accepted in an earlier series at Tygerberg Hospital, another Western Cape hospital.^[8] This similarity might be due to the predominance of psychosocial criteria used to select patients in both series.

Even though in both series age and employment status were both prominent decisive factors, Moosa et.al., had more whites being selected than blacks.^[8] This is in contrast to our results which document more blacks being accepted than non-blacks in univariate analysis. However in multivariate analysis, race is not a predictor for acceptance onto treatment. One may hypothesize that the disparities in access to health have improved over the years in alignment with the government's policy to provide health care for all. The South African renal registry data support this hypothesis as the proportion of black South Africans on dialysis has increased from 31.2% in 1994 to 51.2% in 2012.^[19] This is unfortunately not entirely accurate, as several reports^{[64][65]} have continued to document the inequality in access to health in the new South Africa. However these results show an encouraging trend 20yrs after demise of the apartheid system. Our results may reflect the similarities in socio-economical characteristics among the uninsured South Africans attending a state sponsored hospital. Disparities in access to health, particularly in those uninsured is not a local phenomenon but rather a global concern.^{[14][63]}

Disparity in selecting patients based on employment status has been previously reported in South Africa.^[8] Unemployment was an important predictor of being rejected from the renal replacement therapy program at Groote Schuur. This is no longer a discriminatory factor in the current Western Cape guidelines (Appendix 2). Despite this, the guidelines may still negatively affect unemployed candidates. Acceptance onto the program requires evidence of financial means to regularly arrange for transport to the renal unit, which is part of the criteria. About two thirds (68% of 257 accepted patients) were employed in our cohort. In contrast to our findings only 11.4% of 290,252 patients being prepared for ESKD care in the United States were employed.^[66]

Other socio-demographic factors such as gender, marital status, nationality and area of residence were not predictors of acceptance among presented patients. This adds strengths to the use of current guidelines which do not discriminate against these groups.

Inadequate access to health care probably explains another finding in our audit. The majority of patients presented to our RRT program were in advanced disease stages, forty four percent (N=181) had uremic symptoms and more than half had a serum creatinine concentration above 1000µmol/L (Table 4). Patients who are socioeconomically disadvantaged tend to present late to a nephrologist^{[67][68]} and have less than optimal outcome on treatment.^[69] This is consistent with the advanced presentation of patients in our series, as over half of the presented patients 51% (N=242) came from the lowest

socioeconomic areas of Cape Town. This work indirectly reveals the challenges in the current health system of the Western Cape.

The difficulty in early diagnosis was also seen in HIV positive patients. In our cohort, HIV positive patients were under-represented. HIV positive patients accounted for only 10% of all new patients presented to the selection committee. Similarly in a study looking at the outcomes of rationing among ESKD patients at Groote Schuur Hospital (GSH), only 12.5% had HIVAN.^[4] The number of HIV patients in these cohorts is likely lower than expected. This assumption is based on another GSH study which showed that 44% of all patients with Nephrotic syndrome had HIVAN. And particularly because these HIVAN patients had severely impaired renal function.^[70] Under representation of HIV positive patients arises from the fact that most had outright exclusion criteria. In other words, they had uncontrolled HIV disease. One may infer that this demonstrates the challenges of early diagnosis and treatment of HIV in South Africa. Early diagnosis and management of HIV would allow more HIV positive candidates to be considered for dialysis and transplantation. It should be noted that HIV status was not a predictor of acceptance onto the program among new patients presented (Table 6).

New guidelines for selection were introduced in 2010. The impact of their use at Groote Schuur was examined in this work. There was a trend towards increased HIV positive patients being accepted (Table 8). This finding likely represents the increase in burden, as stable HIV positive patients were accepted since 2009. The absolute number of patients accepted increased between 2008 and 2012 ($p=0.025$) but when the implementation periods were compared no difference was noted (Figure 3, Table 8). This is because during the year 2009 there was an abrupt increase in the number transplants associated with increased acceptance rates. In overall, the trend was towards increased acceptance rates in keeping with the prioritization policy. This policy, which allows for the best candidates (category 1) to be accepted regardless of the available resources, increased the number of patients treated.

Study Limitations

The retrospective study design depended on available reports which had some missing data. A detailed record of the socio economic status of patients could not be described. These results may not be generalized to the whole South African population because there is a significant dialysis population in the private sector. The private sector has a different population distribution compared to the state dialysis patients.

8.0 Conclusion and Recommendations

Twenty years after the end of apartheid, South Africa has made improvements in disparities to access of dialysis despite resource challenges. In the setting of resource limitation, rationing of dialysis becomes unavoidable in running a sustainable program. Efforts to allocate more resources should continue in view of the loss of young and potential productive life. Advanced presentation of patients with ESRD represents challenges in early diagnosis and referral in the current system. Community screening programs and improved access to knowledgeable clinicians at the primary level is advocated. The use of new selection guidelines have not led to increase in selection inequalities.

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Appendixes

Appendix 1 Case Record Form

Characteristics and outcomes of patients assessed for the renal replacement therapy at
Groote Schuur Hospital.

PART 1: Demographics	S/No: ID code.....
Age	Sex <i>Male/Female/Unknown</i>
Marital Status <i>married/single/divorced/widowed</i>	Employment Status <i>employed/unemployed/housewife</i>
Race	Residence
Religion	
PART2: Clinical characteristics	
P/Complaint	BMI
Serology: HIV(CD4) HBSag CMV	Main Diagnosis and Co morbidities
Late Referral yes/no Referring institute	Eligibility for Kidney transplantation <i>Contraindication absent or present</i>
PART3: Other Social Characteristics	
Home conditions: Favorable/unfavorable	
Social Support: Adequate/Inadequate	
Insight: strong/weak History of Noncompliance to treatment y/n	
Substance Abuse: yes/no Type and Duration	
PART4: Outcome of Assessment	
Category: Medical Social Final	
Acceptance yes/no	Appeal : yes/no Outcome of appeal:

Appendix 2: Prioritization Policy

The Western Cape Government has drawn up guidelines to prioritize eligibility into the renal replacement programs (3). The following are the criteria used to categorize patients.

All patients in whom the diagnosis of end-stage or advanced chronic kidney disease is made will undergo formal assessment. This process will stream patients into 3 groups:

- Category 1. Patients with this priority rating must be accommodated on the dialysis and transplant programme. Resources will always be found to treat these patients.
- Category 2. Patients with this priority rating will be accommodated on the programme only if resources allow, with priority to the category 2 patients waiting the longest and who have the best chance of good outcomes.
- Category 3. Patients in Category 3 will be offered optimal conservative treatment, are not eligible for Categories 1 or 2 and will not be offered renal replacement therapy

Category 1:

Patients in this category are considered to potentially have the best possible outcome and would derive maximum benefit with the lowest risk of treatment failure. In addition to meeting the relevant requirements of Category 2 (and not been excluded by any Category 3 factor), a patient in this category must be assessed against, and meet the following constellation of factors:

- o Age. 50 years;
- o BMI less than 30 kg/m²;
- o HIV negative;
- o Hepatitis B Surface Antigen (HBsAg) negative.

These factors, taken together and considering the patients overall medical condition, will guide the decision on selecting patients for Category 1.

Category 2:

Patients in this category may be eligible for treatment provided resources allow. The following factors improve a patient's chance of being offered treatment:

Social Factors

Good home circumstances (including access to storage space, running water, sanitation and electricity), needed to succeed with dialysis and transplantation;

The patient is well-motivated and has access to a good social support system required to do well on dialysis and transplantation, and Proximity to and/or evidence of financial means or other capability to regularly arrange transport to a Renal unit as frequently as this may be needed (the unit is unable to pay for or provide such transport).

The following factors, taken together, reduce the chances of being offered treatment:

Medical Factors

Above age 50 years;

BMI 30-35 kg/m²;

Hypertension with severe left ventricular dysfunction or other severe target organ damage;

HBSag/HCV positive with no cirrhosis;

Smoking;

Diabetes mellitus;

HIV+ patients whose CD4+ T cell count. 200/ml, have an undetectable viral load and, if on antiretroviral (ARV) treatment, demonstrated good adherence and clinical response within 6 months;

First presentation with ESKF requiring urgent dialysis;

Comorbid disease e.g. stable ischemic heart disease;

Previous kidney transplant.

These factors, taken together and considering the patients overall medical condition, will guide the decision on offering treatment but no single factor will automatically exclude patients from treatment. The extent to which patients have properties that resemble those of category one patients, the greater the likelihood that they will be accepted; conversely the greater the number of unfavorable factors the lower chances of acceptance.

Category 3

Kidneys are a very scarce resource and should be allocated to patients who will derive most benefit from the transplant. Any condition or circumstance which compromises the medium-long term survival of a patient or the graft will exclude the patient from transplantation and selection for Category 2 or Category 1.

Any one of the following factors excludes patients:

Renal transplantation is contraindicated or carries unacceptable risks;

AIDS or HIV infection other than HIV+ patients with the medical characteristics described in category 2;

Age 60 years;

Active substance abuse or dependency;

Morbid obesity (BMI . 35 kg/m²);

HBeAg positive or cirrhosis;

Diabetes mellitus and aged >50 years;

Active, uncontrollable malignancy with short life expectancy;

Advanced, irreversible progressive disease of vital organs such as:

- o cardiac, cerebrovascular or peripheral vascular disease

- o liver disease

- o lung disease

- o unresponsive infections

Psychological Exclusion Criteria

- o Any form of serious mental illness or incapacity which, as shown by psychiatric and medical examination, would preclude the patient and/or family or available support group from successfully managing the patient, considering his/her impairment, through dialysis, a transplant, and extended follow up care;

Habitual Non-Adherence

- o Patients with habitual non-adherence to any medical treatment.

UNIVERSITY OF CAPE TOWN



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28 February 2013

HREC REF: 085/2013

Dr K Kilonzo
c/o Prof B Rayner
Renal Department
Division of Nephrology
NGSH

Dear Dr Kilonzo

PROJECT TITLE: CHARACTERISTICS AND OUTCOMES OF PATIENTS ASSESSED FOR THE RENAL REPLACEMENT THERAPY AT GROOTE SCHUUR HOSPITAL

Thank you for addressing the issues raised Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above mentioned sub- study.

Approval is granted for one year till the 28 February 2014.

Please submit a progress form, using the standardised Annual Report Form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

sAriefdien



GROOTE SCHUUR HOSPITAL

Enquiries: Dr Bhavna Patel

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Dr Kajiru Kilonzo
c/o Prof B Rayner
Senior Registrar
Renal Unit
Groote Schuur Hospital

E-mail: KLNKAJ001@myuct.ac.za

Dear Dr Kilonzo

RESEARCH PROJECT: CHARACTERISTICS AND OUTCOMES OF PATIENTS ASSESSED FOR RENAL REPLACEMENT THERAPY AT GROOTE SCHUUR HOSPITAL

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research.

Please note the following:

- a) Your research may not interfere with normal patient care
- b) Hospital staff may not be asked to assist with the research.
- c) No hospital consumables and stationary may be used.
- d) **No patient folders may be removed from the premises or be inaccessible.**
- e) Please introduce yourself to the person in charge of an area before commencing.
- f) Please discuss the study with the Head of Radiation Oncology before commencing.
- g) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
- h) Confidentiality must be maintained at all times.

I would like to wish you every success with the project.

Yours sincerely

DR BHAVNA PATEL
CHIEF EXECUTIVE OFFICER
Date: 2 October 2013

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PATIENT: _____ HOSPITAL NUMBER: _____ D/ T/ Y: _____	CATEGORY 3 Advanced, irreversible progressive disease of vital organs such as: ° Cardiac, cerebrovascular or peripheral vascular disease ° Liver disease ° Lung disease ° Unresponsive infections ° Psychological Exclusion Criteria: ° Any form of mental illness results in diminished capacity for patient to take responsibility for their actions. ° Habitual Non-Adherence: ° Patient with habitual non-adherence with any medical treatment.	CATEGORY 2 MEDICAL Hypertension with severe left ventricular hypertrophy or other target organ damage ° HBsAg/HCV positive and no cirrhosis ° Smoking ° Diabetes Mellitus ° HIV+ providing CD4 count >200 and undetectable viral load; if on antiretroviral (ARV) treatment, demonstrated good adherence and clinical response within 6 months ° First presentation with ESKF requiring urgent dialysis ° Comorbid disease e.g. stable ischaemic heart disease ° BMI 30-35kg/m ²	CATEGORY 1 Patient has no Category 2 or 3 factors and satisfies <u>all</u> the following factors: ° Age <50 years ° BMI less than 30kg/m ² ° Gainfully employed* ° HIV negative ° Hepatitis B Surface Antigen (HBsAg) negative
CATEGORY 2 Any <u>one</u> of the following factors excludes patient: ° Renal transplantation is contraindicated or carries unacceptable risks. ° AIDS or HIV infection other than patients described in category ° Age >60 years (except under exceptional conditions) ° Active substance abuse or dependency ° Morbid obesity (BMI >35kg/m ²) ° HBsAg positive or cirrhosis ° Active, uncontrollable malignancy with short life expectancy ° Non-South African citizen	CATEGORY 3 Social ° Age 50-60 years ° No minor dependents ° No living kidney donor ° Poor home circumstances, including lack of access to storage space, running water, sanitation and electricity ° Convicted criminal ° Not gainfully employed ° Illiteracy ° Poor social network/support ° No proximity to dialysis unit ° Lack of easy telephone/cellphone access	Accepted <input type="checkbox"/> Not Accepted <input type="checkbox"/> Wait <input type="checkbox"/> Provisionally Accepted <input type="checkbox"/> Provisionally Not Accepted <input type="checkbox"/> Haemo <input type="checkbox"/> PD <input type="checkbox"/> Family Transplant <input type="checkbox"/> HIV Pos <input type="checkbox"/> Hep B Pos <input type="checkbox"/> Hep B Neg <input type="checkbox"/> HIV Neg <input type="checkbox"/> Hep C Pos <input type="checkbox"/> Hep C Neg <input type="checkbox"/> CREATININE: _____ CATEGORY: _____ PRIMARY RENAL DISEASE: _____	

GROOTE SCHUUR HOSPITAL SOCIAL WORK DEPARTMENT

PSYCHO-SOCIAL ASSESSMENT

This outline is only a guideline. At all times the individual patient must be taken into consideration when assessing for renal replacement therapy.

1. **Identifying details:** Name, age, sex, address, occupation and marital status.
2. **Family Background:** The origins of the family, movements of family and patient till present day. How the patient experienced his/her childhood within the family and community/school. Any educational problems or/and behavioural difficulties and the effects thereof during childhood. Family composition including parents and siblings.
3. **Educational history:** The highest educational qualification achieved. If the patient failed to complete schooling or courses, state the reasons. State the relationships between patient, teachers and schoolmates.
4. **Employment:** Full employment history and current employment. Contact numbers and names of employer and details of employer's knowledge of illness and their willingness to co-operate with sick leave. We encourage our patients to maintain interest in employment for post transplantation.
5. **Income:** Joint income (Net) of patient and spouse or partners.
6. **Housing:** Please provide description of home, size and availability of water and bathroom facilities. Also state distance of home from treating hospital or doctor. State amount of people residing in the patient's home.
7. **Habits:** Cigarette smoking and alcohol use and abuse. (patterns and amounts) Also state the abuse of prescription and illegal drugs. If the patient has an alcohol or drug problem, our protocol is that he/she must show commitment to stopping and includes a recognized treatment programme for at least 6 months. This will show commitment to the programme both pre and post transplant.
8. **Hobbies and Interests:** State current as well as previous interest and hobbies. This can include sport as well as community activities.

9. **Support Systems:** Give a detailed description of the patients' support system at home including religious support. As the patient will be required to stay in Cape Town for a lengthy period (if outside the Western Cape), provide information of support in Cape Town as well as the need for accommodation and if spouse or partner is able to travel with patient.

10. **Relationships:** Provide an account of the patient's current relationships, problems in the past and the means of resolving conflict in relationship. If the patient is not currently in a relationship, provide history of past relationships and reasons for break-ups especially divorce. If the patient has children state relationships with them. Mention any problems that currently exist in the patient's relationships.

11. **Coping mechanisms:** Provide details of the patient's manner in coping with previous crisis and stresses. Has patient resolved previous losses that may have been experienced? How is the patient coping with his current diagnosis?

12. **Psychiatric History:** State the nature, duration and treatment of any psychiatric illness. If patient has a history of depression, please provide treatment methodology.

13. **Basic Personality:** Mention patient's current mood as well as interpersonal relationship, attitude towards and description of self.

14. **Identifying Problems:** Identify any problem areas that may need attention and what intervention is planned from your part.

15. **Evaluation and Recommendation:** Concentrate on the internal and external resources of the patient in light of the above information.

ANDRE DE VOS
Manager
Social Services
GROOTE SCHUUR HOSPITAL
17 January 2012